



October 2, 2006

The Honorable Henry A. Waxman
U.S. House of Representatives
Washington, DC 205156

Dear Mr. Waxman:

The National Organization for Rare Disorders (NORD) wholeheartedly supports your legislation that would give the Food and Drug Administration the authority to review and approve applications for biological products that are “comparable” to previously approved biological therapies.

Millions of Americans affected by one of the 6,000 known rare diseases rely on the lifesaving properties of biologics to sustain or improve the quality of their lives – twenty-two percent of the 295 orphan drugs on the market today are biologics. For many chronic rare diseases, the cost of treatment for just one year is equivalent to buying a new house each year for the rest of their lives.

Competition generates innovation, but because there is no regulatory pathway within the FDA to approve follow-on biologics, there is little or no incentive for manufacturers to develop improved versions of their products (i.e. changing an intravenous to an injectible or pill, or making long-acting versions that require decreased dosage). Consequently, the lack of competition in biologics impedes the development of new cutting-edge advances for the treatment of rare diseases.

NORD and the 25 million men, women and children we represent deeply appreciate your efforts to provide the FDA a pathway to create a well-defined regulatory process based on vigorous scientific standards for comparable biologic product development.

We look forward to the opportunity to work with you in the coming Congress.

Sincerely,

Abbey S. Meyers
President

ASM:aa

cc: Carolyn Asbury, Ph.D., NORD Chair
Diane E. Dorman, NORD Vice President for Public Policy